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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/686,997	10/12/2000	Olivier De Lacharriere	196726US0	5836

22850 7590 10/07/2003

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.  
1940 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER
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WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 10/07/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/686,997

Applicant(s)

DE LACHARRIERE ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on April 15, & July 21, 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12,13,16-24 and 27-45 is/are pending in the application.
- 4a) Of the above claim(s) 36-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12,13, 16-24, 27-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. Claims 36-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 17.

2. Applicant's election with traverse of invention group II in Paper No. 17 is acknowledged. The traversal is on the ground(s) that it has not been established that inventions are not disclosed as capable of use together. This is not found persuasive because the inventions have distinct functions and applications as stated in the prior office action. It is not seen how these inventions may be use together, e.g., for person without abnormal pigmentation.

The requirement is still deemed proper and is therefore made FINAL.

3. As to the species election, prior art reveals that the difference in structures of the compounds herein does not make them distinct from each other since they all have the basic structure and the same biological function. Therefore, applicants' arguments are persuasive and the species election is herein withdrawn.

4. The terminal disclaimer filed on April 15 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,486,147 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Claim Rejections 35 U.S.C. 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 12, 13, 16-24, and 27-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 12 and 23 are rejected for being confusing due to the recitations of "5-androstene-3 $\beta$ , 17 $\beta$ -diol sulfate" and "5-androstenediol sulfate." These two phrases denote the same compound (s). These recitations are confusing for reasons as stated in the prior office action.

***Claim Rejections 35 U.S.C. 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 12, 13, 16-18, 23-24, 27-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Orentreich (IDS).

Orentreich teach a method of treating skin condition by applying to the skin a composition comprising about 1% of DHEA or its derivatives and a keratolytic agent. See, particularly, the abstract, the examples, and the claims. Such treatment would have inherently lightening the skin or pro-pigmenting superficial body growths. Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, supra, the claims are directed to depigmentation or lightening of skin with old and well known cosmetic compositions. It is now well settled law that administering compounds

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inherently possessing a therapeutic utility anticipates claims directed to such therapeutic use.

Arguments that such therapeutic use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex parte Novitski*, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975)". In the instant application, Applicants' failure to distance the proffered claims from the anticipated therapeutic utility, renders such claims anticipated by the prior inherent use.

10. Claims 12, 13, 16-18, 23-24, 27-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenbaum (US Patent 5,869,090).

Rosenbaum teaches a method of treating skin conditions by applying a composition comprising about 1% of DHEA to the skin. See, particularly, the abstract, examples 9-13 and claims 19 and 25. As discussed above, such treatment would have inherently lightening the skin or propigmenting superficial body growths.

#### ***Response to the Arguments***

Applicants' amendments and remarks submitted April 15, 2003 have been fully considered, but are moot in view of the new ground rejections.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Patent Examiner

A handwritten signature in black ink, appearing to read 'Shengjun Wang', is written over a faint, rectangular stamp that contains the name 'SHENGJUN WANG' in all capital letters.

Shengjun Wang

October 6, 2003